



Patient Information Sheet

Duloxetine hydrochloride (marketed at Cymbalta)

This is a summary of the most important information about Cymbalta. For details, talk to your healthcare professional.

FDA ALERT [05/2005] – Suicidal Thoughts or Actions in Children

Patients with depression or other mental illnesses often think about or attempt suicide. Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior should be evaluated by their healthcare professional right away.

Although Cymbalta is prescribed for children, FDA has not approved Cymbalta for use in children.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What Is Cymbalta?

Cymbalta is in a class of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). Cymbalta is used to treat depression.

Who Should Not Take Cymbalta?

- **Never take Cymbalta if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking Cymbalta close in time to an MAOI can result in serious, sometimes fatal, reactions, including:**
 - High body temperature
 - Coma
 - Seizures (convulsions)

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid), and other brands.

- Never take Cymbalta if you have uncontrolled narrow-angle glaucoma (disease causing increased pressure in the eye).
- Do not take Cymbalta if you have serious kidney or liver disease or drink alcohol excessively.

What Are The Risks?

- **Suicidal thoughts or actions:** See FDA Alert.

- **Stopping Cymbalta:** Do not stop taking Cymbalta suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.
- **Possible liver damage:** Cymbalta may cause liver damage. **Do not drink alcohol** while taking Cymbalta because this can make liver damage worse.
- **Blood pressure:** Your blood pressure may increase.
- **Mania:** You may become unusually hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion), even if you are not taking Cymbalta close in time with a MAOI.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because babies delivered to mothers taking Cymbalta late in pregnancy have developed problems, such as difficulty breathing and feeding.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Other side effects** include nausea, dry mouth, constipation, decreased appetite, fatigue, sleepiness, and increased sweating.
- **Tell your healthcare professional** about all your medical conditions, especially if you have liver or kidney disease, or glaucoma. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

Are There Any Interactions With Drugs or Foods?

- Cymbalta may interact with medicines other than the ones already mentioned in this information sheet, causing serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take, especially those used to treat anxiety, mental illness, depression, infections, or heart problems.
- **Do not drink alcohol** while taking Cymbalta.

How Do I Take Cymbalta?

- Cymbalta is taken by mouth, with or without food, exactly as prescribed by your healthcare professional.
- Swallow Cymbalta capsules whole. Do not crush or chew them. Do **not** open the capsule and mix the contents with liquid or food.

Is There Anything Else I Need to Know?

You can get more information about antidepressants at:

<http://www.fda.gov/cder/drug/antidepressants/default.htm>

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